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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,734	07/13/2001	Yoshikatsu Kodama	011900-310	9324

7590

09/24/2002

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/903,734

Applicant(s)

KODAMA ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, drawn to a composition comprising IgY and inhibitor of gastric acid secretion.
  - II. Claims 3-4, drawn to a pharmaceutical composition comprising IgY antibody, an inhibitor of gastric acid secretion, a pharmaceutically acceptable carrier.
  - III. Claim 5, drawn to a method for inhibiting Helicobacter Pylori(H.Pylori) adhesion, comprising orally administering of a therapeutically effective amount of IgY and an inhibitor of gastric acid secretion.
  - IV. Claim 6, drawn to a method of preventing and/or treating a disease by Helicobacter pylori using an effective amount of (i) IgY antibody (ii) an inhibitor of gastric acid secretion.
2. Inventions I-II and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

3. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

4. Inventions I and II are unrelated. Inventions are unrelated because the inhibitor composition do not require in-vivo study whereas a pharmaceutical composition requires not only in vitro but also in-vivo study to prove the pharmaceutical efficacy including phamakokinetic and pharmacodynamic.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II-III or IV obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper. For instance, a composition for the inhibition of H. pylori adhesion does not guarantee the colonization of H.pylori. Since the antibody is body-produced material, it is critical to prove in vivo efficacy including compatibility(see EP1010434, columns 6-7, in *vitro* vs In *vivo* experiment). Thus the inhibitor composition is properly restricted from the pharmaceutical composition which has proved its pharmcaceutic in-vivo efficacy.

For instance, H. Pylori adhesion could be inhibited by materially different product (e.g. plaunotol(a drug extracted from Plau-noi tree) , see Takagi et al, enclosed in PTO-892). The treatment or prevention of diseases either caused by or associated with H.pylori can be treated by materially different product (e.g. a combination(Prevac™) of antibacterial(clarithromycin) and an inhibitor of gastric acid secretion(e,g, omeprazole), or a combination of antibody(from egg yolk) and lactic acid(EP877032)) .

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
September 22, 2002  
Art unit 1614